

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2002D-0326]

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International Cooperation on Harmonization of Technical Requirements for Approval of Veterinary Medicinal Products; Final Guidance for Industry on Studies to Evaluate the Safety of Residues of Veterinary Drugs in Human Food: General Approach to Testing; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; availability.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a guidance for industry (#149) entitled “Studies to Evaluate the Safety of Residues of Veterinary Drugs in Human Food: General Approach to Testing” (VICH GL33). This guidance has been developed by the International Cooperation on Harmonization of Technical Requirements for Registration of Veterinary Medicinal Products (VICH). This guidance outlines a recommended testing approach to assure human food safety following the consumption of food products derived from animals treated with veterinary drugs.

DATES: Submit written or electronic comments at any time.

ADDRESSES: Submit written requests for single copies of the guidance to the Communications Staff (HFV-12), Center for Veterinary Medicine, Food and Drug Administration, 7519 Standish Pl., Rockville, MD 20855. Send one self-addressed adhesive label to assist that office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document.

Submit written comments on the guidance to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to <http://www.fda.gov/dockets/ecomments>. Comments should be identified with the full title of the guidance and the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Louis T. Mulligan, Center for Veterinary Medicine (HFV–153), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–827–6984, e-mail: lmulliga@cvm.fda.gov.

SUPPLEMENTARY INFORMATION:

I. Background

In recent years, many important initiatives have been undertaken by regulatory authorities and industry associations to promote the international harmonization of regulatory requirements. FDA has participated in efforts to enhance harmonization and has expressed its commitment to seek scientifically based harmonized technical procedures for the development of pharmaceutical products. One of the goals of harmonization is to identify and then reduce differences in technical requirements for drug development among regulatory agencies in different countries.

FDA has actively participated in the International Conference on Harmonization of Technical Requirements for Approval of Pharmaceuticals for Human Use for several years to develop harmonized technical requirements for the approval of human pharmaceutical and biological products among the European Union, Japan, and the United States. The VICH is a parallel initiative for veterinary medicinal products. The VICH is concerned with developing harmonized technical requirements for the approval of veterinary medicinal

products in the European Union, Japan, and the United States, and includes input from both regulatory and industry representatives.

The VICH Steering Committee is composed of member representatives from the European Commission, European Medicines Evaluation Agency; European Federation of Animal Health; Committee on Veterinary Medicinal Products; the FDA; the U.S. Department of Agriculture; the Animal Health Institute; the Japanese Veterinary Pharmaceutical Association; the Japanese Association of Veterinary Biologics; and the Japanese Ministry of Agriculture, Forestry and Fisheries.

Four observers are eligible to participate in the VICH Steering Committee: One representative from the Government of Australia/New Zealand, one representative from the industry in Australia/New Zealand, one representative from the Government of Canada, and one representative from the industry of Canada. The VICH Secretariat, which coordinates the preparation of documentation, is provided by the International Federation for Animal Health (IFAH). An IFAH representative also participates in the VICH Steering Committee meetings.

II. Guidance on General Testing

In the **Federal Register** of September 4, 2002 (67 FR 56570), FDA published the notice of availability of the VICH draft guidance, giving interested persons until October 4, 2002, to submit comments. After consideration of comments received, the draft guidance was changed in response to the comments and submitted to the VICH Steering Committee. At a meeting held on October 10 and 11, 2002, the VICH Steering Committee endorsed the final guidance for industry, VICH GL33.

Existing toxicological testing recommendations for veterinary drugs have evolved from the toxicological tests for human medicines, food additives, and pesticides. The following guidance was developed to include tests particularly relevant to the identification of a no-observable adverse effect level (NOAEL) for veterinary drugs. The scope of this guidance is to identify the following tests: (1) Basic tests recommended for all new animal drugs used in food-producing animals in order to assess the safety of drug residues present in human food; (2) additional tests recommended based on specific toxicological concerns associated with the structure, class, mode of action, etc., of the drug; and (3) special tests that might be useful in the evaluation of the relevance or the interpretation of data obtained in the basic or additional tests.

III. Significance of Guidance

This document, developed under the VICH process, has been revised to conform to FDA's good guidance practices regulation (21 CFR 10.115). For example, the document has been designated "guidance" rather than "guideline." Because guidance documents are not binding, unless specifically supported by statute or regulation, mandatory words such as "must," "shall," and "will" in the original VICH documents have been substituted with "should."

This guidance document represents the agency's current thinking to establish the safety of veterinary drug residues in human food in a variety of toxicological evaluations. This guidance does not create or confer any rights for or on any person and will not operate to bind FDA or the public. An alternative method may be used as long as it satisfies the requirements of applicable statutes and regulations.

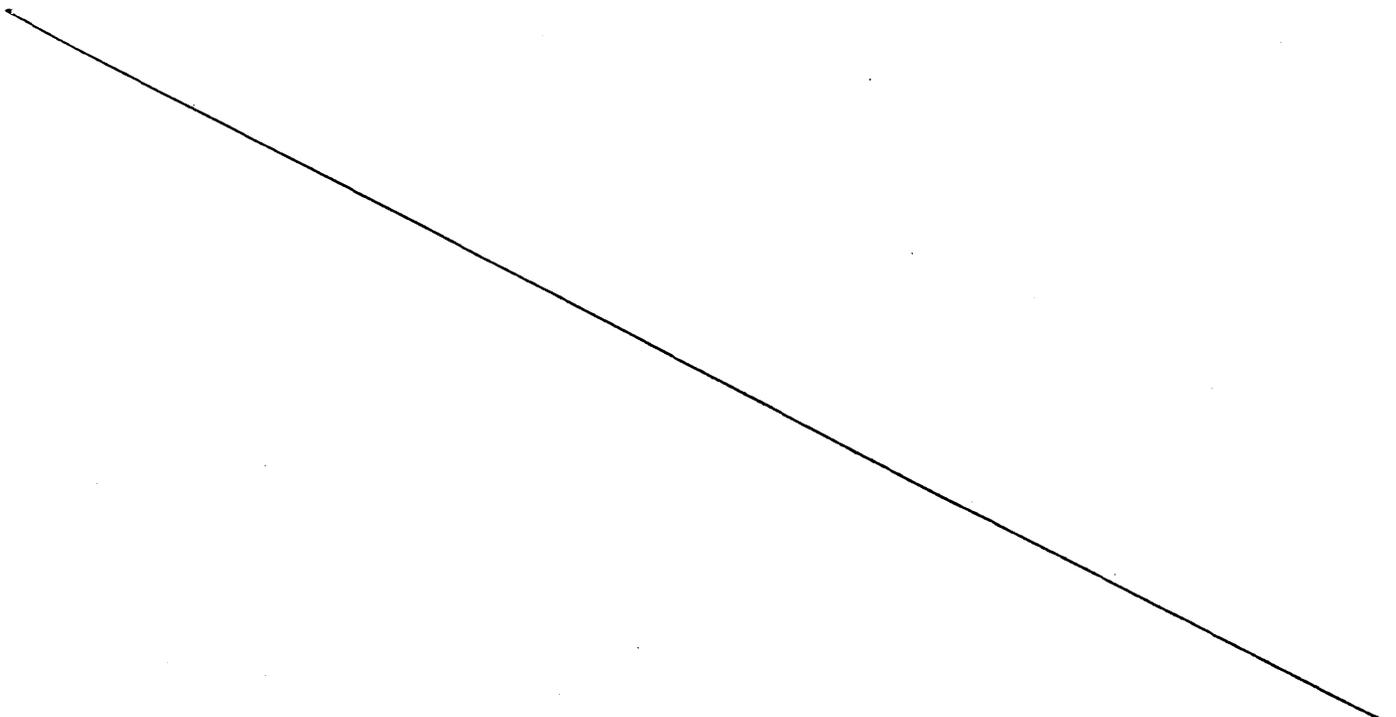
IV. Comments

As with all of FDA's guidances, the public is encouraged to submit written or electronic comments pertinent to this guidance. FDA will periodically review the comments in the docket and, where appropriate, will amend the guidance. The agency will notify the public of any such amendments through a notice in the **Federal Register**.

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments regarding this document. Submit a single copy of electronic comments or two paper copies of any mailed comments, except that individuals may submit one paper copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

V. Electronic Access

Copies of the guidance document entitled "Studies to Evaluate the Safety of Residues of Veterinary Drugs in Human Food: General Approach to Testing"



(VICHGL33) may be obtained on the Internet from the CVM home page at <http://www.fda.gov/cvm>.

Dated: May 13 2004

May 13, 2004.



William K. Hubbard,
Associate Commissioner for Policy and Planning.

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